



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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### TELECONFERENCE MEMORANDUM

Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and Research

March 15, 2007  
12:00 pm EST

FDA participants  
Keith Wonnacott  
Thomas Finn

Dendreon Participants  
Liz Smith  
Connie Spooner  
Nicole Provost

#### Summary

Dendreon requested to talk to us about two main issues. First, figures Dendreon would like to redact from the briefing document. Second, slides Dendreon would like to potentially use at the advisory committee.

1. Dendreon informed us that they would like to redact Table 1 and Figure 5 from the briefing document. We discussed possible alternatives and Dendreon decided they would like to include an alternative figure for public display. We told them to go ahead and submit any alternative and we would look at it. We said that having an alternative might be helpful for our presentation at the advisory committee meeting.

2. Dendreon sent several slides that they would like to use at the advisory committee meeting by email in advance of the telecon. I informed them the general feel of the office was that they should not present data that is not included in the BLA. They said the data was mostly in the BLA, just presented in a different manner. I informed them that they shouldn't use the data that is not in the BLA and that they should consult with the clinical reviewers about the different presentation of survival data because that data is in the clinical section of the BLA. I agreed it would be acceptable if they used the upregulation data on the salvage therapy since that data is now in the BLA.

There was some other scientific discussion about the slides that were sent.

The call lasted about 45 minutes.